REMARKS

Reconsideration of the above-identified application is respectfully requested.

Claims 7-10 and 13 have been canceled. Claims 39-41 have been amended. No new matter has been added as a result of these amendments.

Rejection of Claims 35-37 and 39-45 under 35 U.S.C. Section 101

Claims 35-37 and 39-45 are rejected under 35 U.S.C. Section 101 as not being supported by a specific asserted or utility or a well-established utility. Applicants respectfully traverse this rejection.

The present invention possesses a specific and substantial utility that is credible. More specifically, as discussed in Example 1 on pages 57-58 of the specification, EST's corresponding to the consensus sequence of LS147 were found in 35.7% (15 of 42) of lung tissues. EST's corresponding to the consensus sequence of SEQ ID NO:7 (or fragments thereof) were not found in **any** (0 of 610) of the other non-lung tissues. LS147 was only found by Applicants to be expressed in lung tissue. In fact, the consensus sequence or fragment thereof was found more than 35 times more often in lung than in non-lung tissues.

Figure 3, which is a Northern blot and which confirms the data described above in Example 1, shows that the LS147 probe detected an approximately 0.5kb RNA in the lung sample (lane 7) but not in any of the other eleven non-lung RNA samples (lanes 1-6 and 8-12).

As discussed in Applicants previous Amendments, the detection of LS147 outside of the lung is diagnostically useful as it serves as an indicator that the host (lung) is in a

diseased state. The identification of markers to identify disease in patients is extremely valuable. Several different categories of markers are known that can be used to identify disease. One such category of markers are those that are genes that are expressed in a tissue specific fashion but appear in an inappropriate body compartment when that tissue is diseased (See, specification, page 4, lines 17-33). The expression of a marker in a tissue or body compartment where its normal occurrence is very low or non-existent indicates that the host tissue is diseased and that the marker has escaped from its host tissue. Examples of markers that fall into this category are prostate specific antigen (PSA) and carcinoembryonic antigen (CEA). PSA is normally secreted at high levels into the seminal fluid and is present in very low levels in the blood of men with normal prostates. However, in patients with diseases of the prostate, including benign prostatic hyperplasia (BPH) or adenocarcinoma of the prostate, the level of PSA is markedly elevated in the blood and is a strong indication of disease of the prostate.

Similarly, CEA is a normal component of the inner lining of the colon and is present stool and in blood at low levels in people without disease of the colon. However, in disease of the colon, including inflammatory bowel disease and adenocarcinoma of the colon, the concentration of CEA is markedly elevated in the blood plasma or serum of many patients and is an indicator of disease of that tissue (such as colorectal cancer).

Additionally, like LS147, PSA and CEA are expressed in a few tissues other than the colon and prostate. Nonetheless, these markers are still recognized as useful in the diagnosis of disease of their primary tissue of origin due to their strong tissue selectivity.

Moreover, as discussed in the Declaration of Dr. Paula Friedman submitted in Applicants last Amendment, the specificity of LS147 closely resembles the tissue specificity of PSA and CEA and in fact, LS147 is even more tissue-specific than either CEA and PSA. Therefore, to one of ordinary skill in the art, the presence of LS147 outside of the lung would indicate cancer development of that tissue, just as the presence

of CEA and PSA outside of their respective tissues indicates cancer of the colon and prostate, respectively.

35 U.S.C. Section 101 has two purposes. First, 35 U.S.C. Section 101 defines the categories of inventions that are eligible for patent protection. An invention that is not a machine, an article of manufacture, a composition or a process cannot be patented. Second, 35 U.S.C. Section 101 serves to ensure that patents are granted on only those inventions that are "useful". *Manual of Patent Examining Procedure* Section 2107.01 (8th Edition, August 2001). Therefore, to satisfy the requirements of 35 U.S.C. Section 101, an applicant must claim an invention that is statutory subject matter and must show that the claimed invention is "useful" for some purpose, either explicitly or implicitly. *Id.*

To be "useful" for some purpose, the invention must have a specific and substantial utility (i.e. "a practical utility"). A "specific" utility is specific to the subject matter claimed (versus a "general utility" that would be applicable to a broad class of invention). A "substantial utility" defines a "real world" use. Not only must the invention have a specific and substantial utility, but this utility must be credible. Credibility is assessed from the perspective of one of ordinary skill in the art in view of the disclosure and any other evidence of record (e.g. test data, affidavits or declarations from experts in the art, patents or printed publications). *Manual of Patent Examining Procedure* Section 2107 (8th Edition, August 2001). An applicant need only provide one credible assertion of specific and substantial utility for each claimed invention to satisfy the utility requirement. *Id.*

To properly reject a claimed invention under 35 U.S.C. Section 101, the Examiner must (a) make a *prima facie* showing that the claimed invention lacks utility, and (b) provide a sufficient evidentiary basis for factual assumptions relied upon in establishing the *prima facie* showing (*Manual of Patent Examining Procedure* Section 2107.02 (8th Edition, August 2001)). The Examiner must do more than question the operability of the

invention. Specifically, the Examiner must set forth factual reasons that would lead one skilled in the art to question the objective truth of the statement of operability. *Id.*

In view of the above arguments and the evidence presented in previous Amendments, Applicants respectfully submit that the Examiner has failed to make a *prima facie* showing that the claimed invention lacks utility. However, even assuming *arguendo* that the Examiner has made a *prima facie* showing that the claimed invention lacks utility, the Examiner has failed to provide a sufficient evidentiary basis for her factual assumptions relied upon in making this showing. Specifically, the Examiner has not provided any evidence refuting or contracting the statements supporting utility made in the Declaration of Dr. Friedman. Clearly, Dr. Friedman is one of ordinary skill in this art.

Therefore, Applicants submit that the rejection of claims 35-37 and 39-45 under 35 U.S.C. Section 101 is improper and should be withdrawn.

Rejection of claims 35-37 and 39-45 Under 35 U.S.C. Section 112, First Paragraph

Claims 35-37 and 39-45 are rejected under 35 U.S.C. Section 112, first paragraph as not being supported by a specific or substantial or credible asserted utility or a well-established utility. Applicants respectfully traverse this rejection.

Applicants herein incorporate by reference their arguments made above in connection with the 35 U.S.C. Section 101 rejection. Therefore, in view of said arguments, Applicants submit that this rejection is improper and should be withdrawn.

Claim Rejections – 35 U.S.C. Section 112, Second Paragraph

Claims 39-40 are rejected under 35 U.S.C. Section 112, second paragraph, as being indefinite. Specifically, the Examiner stated that the recitation of "wherein the open reading frame" in claim 39 lacked antecedent basis. Applicants have amended

claim 39 to provide a proper antecedent basis for this claim. Therefore, in view of this amendment, Applicants submit that this rejection has now been obviated and should be withdrawn.

Claim Rejections – 35 U.S.C. Section 101

The Examiner rejected claims 40-41 as not being written to sufficiently distinguish over cells that exist naturally because these claims do not particularly point out any non-naturally occurring differences between the claimed products and the naturally occurring products. Applicants have amended claims 40 and 41 to refer to "an isolated" cell as suggested by the Examiner. Applicants thank the Examiner for this helpful suggestion. Therefore, in view of this amendment, Applicants submit that this rejection has now be obviated and should be withdrawn.

Applicants submit that the claims are now in condition for allowance.

Respectfully submitted,
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